In the **Federal Register** of August 29, 2011 (76 FR 53683), FDA announced the availability of the draft guidance entitled ''Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring,'' dated August 2011, and the public was provided with an opportunity to comment on it until November 28, 2011. FDA carefully considered all of the comments received in developing the final guidance. The final guidance includes clarifications and additional detail on some topics. For example, the final guidance includes additional detail on how to perform risk-based monitoring and examples of monitoring techniques.

The final guidance describes strategies for monitoring activities that reflect a modern, risk-based approach that focuses on critical study parameters and relies on a combination of monitoring activities to oversee a study effectively. The guidance also makes recommendations about how to develop monitoring plans and document monitoring activities and includes additional strategies to ensure study quality.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on oversight of clinical investigations—a risk-based approach to monitoring. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance were approved under OMB control numbers 0910–0078, 0910–0014, and 0910–0733.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceREgulatoryInformation/default.htm, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*, or *http://www.regulations.gov.*

Dated: August 1, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–19004 Filed 8–6–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 17, 2013, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center (Rm. 1503), 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Diane Goyette, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *AIDAC@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The purpose of the meeting on October 17, 2013, is to discuss susceptibility interpretive criteria for systemic antibacterial drugs and for dosing recommendations in product labeling. We will seek input on the role of pharmacokinetic data in setting susceptibility interpretive criteria. We will also discuss revising dosing recommendations in product labeling based on pharmacokinetic data and clinical safety and efficacy data.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 2, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 24, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably

accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 25, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Diane Goyette at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 1, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–19036 Filed 8–6–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0779]

Retrospective Review of Draft Guidance Documents Issued Before 2010; Withdrawal of Guidances

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an initiative in the Center for Drug Evaluation and Research (CDER) involving the review of draft guidance documents issued before 2010 to determine their status, and to decide whether those guidances should be withdrawn, revised, or finalized with only minor changes. Guidances that are no longer up to date, and for which more current information is available, will be withdrawn. Guidances that reflect CDER's current thinking, CDER will decide whether to revise or finalize. This notice describes CDER's initiative, announces the first group of guidances to be withdrawn, describes in general terms draft guidances under consideration for revision or finalization, and explains how CDER is making this process as transparent as possible.

DATES: General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit electronic comments on Agency guidance documents to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to Agency guidance documents.

FOR FURTHER INFORMATION CONTACT: Kimberly K. Thomas, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6220, Silver Spring, MD 20993–0002, 301–796–2357, *kimberly.k.thomas@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In September 2000, FDA issued the final rule ''Administrative Practices and Procedures; Good Guidance Practices'' (GGP) (65 FR 56468; September 19, 2000). The GGP regulation describes FDA policies and procedures for the development, issuance, and use of guidance documents and makes these Agency policies and procedures clear to the public. The GGP regulation provides for developing and issuing guidances that set forth initial interpretations of statutory or regulatory requirements, explain changes in interpretation of policies that are of other than minor in nature, or discuss complex scientific issues or highly controversial issues. The GGP regulation also requires that such guidances be issued in draft for public comment before they are finalized (Level 1 guidances). In addition, the GGP regulation explains that FDA will periodically review existing guidance documents to determine whether they need to be changed or withdrawn.

A key component of the GGP regulation is ensuring transparency during guidance development and issuance. Since finalization of the GGP regulation in September 2000, CDER has issued an average of approximately 20 draft guidances each year, seeking public input and carefully considering that input before issuing final versions of the guidances. In many cases, guidances were not finalized most often because of higher staff priorities. However, over the years, because of new information, scientific developments, and emerging technologies, draft guidances were also revised, and reissued or withdrawn.[1]

Recently, CDER launched an initiative to review draft guidance documents published before 2010 to decide which guidances to withdraw, revise, or finalize with only minor changes. CDER is withdrawing draft guidances that are no longer up to date. CDER is also actively reviewing the draft guidances to determine which ones to either revise or finalize. This notice lists the first group of guidances CDER has identified for withdrawal, describes generally what guidances are being reviewed, and describes how CDER will keep the public informed of the guidances that are available with the goal of making the initiative transparent and consistent with the GGP regulation (21 CFR 10.115).

II. Withdrawal of Guidances

CDER has reviewed many draft guidances published before 2010. As a result of this review, CDER identified 23 draft guidances for withdrawal. The guidances are being withdrawn because they are out of date, thus of little use to the pharmaceutical industry. In most cases, FDA has developed other guidances and resources to assist industry with clinical evaluation and requirements for drug approval. The guidances identified for withdrawal relate to these topics:

- Current good manufacturing practice (cGMP) compliance specific to manufacturing, processing, and dose unit sampling and assessment;
- Development of antimicrobial drugs for the treatment of acute bronchitis, bacterial meningitis, bacterial prostatitis, bacterial vaginosis, catheter-related bloodstream infections, febrile neutropenia, gonorrhea, Lyme disease, streptococcal pharyngitis and tonsillitis, uncomplicated urinary tract infections, and vuvlovaginal candidiasis;
- Clinical trials for developing antimicrobial drugs and packaging of

[1] When Level 1 guidances are revised, they are usually issued as draft, version 2s, for public input before being issued in final form. When a guidance needs to be withdrawn, a notice is sometimes published in the **Federal Register** announcing that the guidance has been withdrawn. If no withdrawal announcement is made, CDER maintains a current list of new/revised/withdrawn guidances on the CDER guidance Web page at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*